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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/982,272	12/01/97	KIPFS	T 231/003

EXAMINER

HM11/0928

GANDEL, P.	PAPER NUMBER
ART UNIT	6

1644

DATE MAILED: 09/28/98

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This is a communication from the examiner in charge of your application.  
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OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 DAYS month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned: (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-83 is/are pending in the application.
- ☐ Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-83 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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### DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10, 67 and 83, drawn to methods of altering the immunoreactivity of human cells, classified in Class 435, subclass 455.

II. Claims 11-21 and 68, drawn to methods of treating human neoplasia with transfected cells, classified in Class 424, subclass 93.1.

III. Claim 22, drawn to methods of treating human neoplasia with tranfecting a tumor bed, classified in Class 514, subclass 44.

IV. Claims 23-49 and 69, drawn to gene therapy vectors, cells comprising said vectors, classified in Class 435, subclasses 252.3, 320.1, 326, 455.

V. Claims 50-56, drawn to methods of vaccinating an animals, classified in Class 424, subclass 93.1.

VI. Claims 57-59, 61-66, drawn to a chimeric accessory molecule ligand gene, classified in Class 536, subclass 23.1.

VII. Claim 60, drawn to chimeric accessory molecule ligands, classified in Class 530, subclass 350.

VIII. Claims 70-77, drawn to a method of treating rheumatoid arthritis, classified in Class 514, subclass 44.

IX. Claims 78-82, drawn to a Fas-ligand chimeric accessory molecule, classified in Class 530, subclass 350.

3. Inventions IV and I/II/III/V/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different processes set forth in Groups I/II/III/V/VIII or can be used to produce proteins of interest.

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4. Inventions I/II/III/V/VIII are different methods of use. These inventions require different ingredients, process steps and endpoints to accomplish the use of gene therapy vectors and/or cells. Therefore they are novel and unobvious in view of each other and are patentably distinct.

5. Inventions IV/VI/VII/IX are different products. Genes, vectors, cells, chimeric ligands/proteins are distinct because their structures and modes of action are different. Therefore they are novel and unobvious in view of each other and are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IX is not required for any other group from Groups I-IX and Groups I-IX have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

7. In addition to selecting a Group from above, applicant is required to make a species election as well.

This application contains claims directed to the following patentably distinct species of the claimed inventions of Groups I-VIII: wherein the accessory molecule specificity is:

- A) CD40 ligand,
- B) Fas-ligand,
- C) CD70,
- D) TNF $\alpha$ ,
- E) TNF $\beta$ ,
- F) CD30 ligand,
- G) 4-1BB ligand,
- H) TRAIL, or
- I) nerve growth factor.

These species are distinct because their structures, interactions, modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

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9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.  
Patent Examiner  
Group 1640  
Technology Center 1600  
July 28, 1998





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